

Applicants : Adrian Gilbert et al.
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The Examiner explicitly acknowledged that Inventions I and II are related as product and process of use. The Examiner stated that inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product, referring to MPEP § 806.05(h). The Examiner alleged that in the instant case the product, the pharmaceutical composition, can be used as an immunogen in a process of making monoclonal antibodies, or in a process of affinity purification, as well as in a method for treating autoimmune disease. The Examiner further alleged that because these inventions are distinct for the reasons given above and have allegedly acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is allegedly proper.

In response to this restriction requirement, applicants hereby elect, with traverse, to prosecute Invention I, Claims 1-43, 50-54 and 61, drawn to a pharmaceutical composition comprising copolymer 1 and microcrystalline cellulose, and a process for manufacturing the composition.

Applicants, however, respectfully traverse the Examiner's requirement and request that the Examiner reconsider and withdraw the restriction requirement. Applicants respectfully direct the Examiner's attention to 37 C.F.R. §1.141(b), which states, "If the process of making and the product are not distinct, the process of using may be joined with the claims directed to the product and the process of making the product, even though a showing of distinctness between the product and the process of using the product can be made." The Examiner has grouped

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together the product (claims 1-42) with the process of making (claim 43). Thus, pursuant to 37 C.F.R. §1.141(b), the process of using (Invention II) may be joined with the claims directed to the product and the process of making the product (Invention I), even though a showing of distinctness between the product and the process of using the product can be made.

Additionally, applicants note that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." [Emphasis added]. Applicants request that the restriction requirement be withdrawn because the Inventions are not independent of each other.

Under M.P.E.P. §802.01, "independent," means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation and effect." Applicants maintain that there is a disclosed relationship between Inventions I and II. In fact, the Examiner explicitly acknowledged that the Invention I and Invention II are "related as product and process of use". Specifically, Invention II recites a method for treating an autoimmune disease comprising administering pharmaceutical compositions of Invention I. The method of Invention II is practiced only with the pharmaceutical compositions of Invention I and cannot be practiced with any other composition. Accordingly, the restriction requirement should be withdrawn.

Furthermore, applicants point out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden.

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Applicants assert that the withdrawal of the restriction requirement would not impose a serious burden on the search or examination. A search of the prior art regarding pharmaceutical compositions comprising copolymer 1 and microcrystalline cellulose and processes for manufacturing the compositions would also reveal prior art relevant to uses of the compositions. Given that it would not be a serious burden on the Examiner if restriction were not required, the restriction requirement should be withdrawn.

For all of the above reasons, applicants respectfully requests that the Examiner reconsider and withdraw the restriction requirement and examine claims 1-43, 50-55 and 61 on the merits.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone the number provided below.

No fee is deemed necessary in connection with the filing of this Communication. If any additional fee is required, authorization

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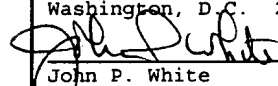
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Respectfully submitted,



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